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*M v*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/508,026	05/05/00	NOMURA	Y JG-YY-4952

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HM22/0507

EXAMINER

REID, S

ART UNIT

PAPER NUMBER

1624

DATE MAILED:

05/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/508,026

Applicant(s)

NOMURA ET AL.

Examiner

Steven M. Reid

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36 is/are allowed.
- 6) ☒ Claim(s) 22-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

Claims 22 – 36 are pending.

### *Response to Amendment*

Applicants' amendment filed 3/23/01 in response to the previous Office Action (paper No. 5 ) is acknowledged. Applicants' amendments have obviated the 35 U.S.C. 112 first paragraph rejection of claims 22 – 36. The rejections of claims 22 – 36 under 35 U.S.C. 103(a) as being unpatentable over Ichihara and JP '182 are traversed by applicants who argue that the examiner did not correctly interpret the chemical structures in both references. Thus instant invention is not obvious over either reference. Upon review of said references, the current Examiner concurs and hereby withdraws both section 103(a) rejections.

Upon further review of pending claims, the current Examiner now presents new grounds of rejection as set forth below.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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1. Claims 22 – 25 and 26 – 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Instant claims are rejected because they are not enabled for the scope of compounds provided by the term “heterocyclic” in the definitions of R<sup>3</sup>, X, and Y<sup>1</sup>. “Heterocyclic” embraces an assortment of cyclic and further fused moieties that may contain any number and type of heteroatoms which are not all enabled. Note *Ex parte Moersch*, 104 USPQ 1122; *In re Howarth*, 210 USPQ 689; *In re Lund*, 153 USPQ 625; and *In re Wiggins*, 179 USPQ 421. Compounds made and tested are directed to a much narrower scope than that being claimed, “heterocyclic” being thienyl, piperadiny, pyridyl, and imidazolyl in these instances. Note *In re Surrey*, 151 USPQ 724 regarding the sufficiency of disclosure for a Markush group in cases directed to structure-sensitive arts. Applicants give no reasonable assurance that representative compounds of the scope being claimed will possess the requisite activity needed to practice the invention.

2. Claims 22 – 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Instant claims are rejected because the terms “comprising”, “heterocyclic”, “carbamoyl”, and “acyl”, where they appear throughout instant claims, are open-ended. Chemical moieties such as aralkyl and heterocyclic-alkyl which are comprised of certain fragments are not limited by claim language to those fragments. The Examiner respectfully suggests that applicants simply change the word “comprising” in each instance to --- consisting of ---. The term “heterocyclic” is not fully defined, in the respect that the number and type of heteroatoms contained in a heterocyclic group,

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and the structure thereof, are not set forth. A *divalent* carbamoyl group -  $\text{-C(O)NH-}$  - is a possible value for *monovalent* substituents on  $\text{R}_1 - \text{R}_4$  and thus leaves open to speculation what else is bound to the carbamoyl group. For the same reason, acyl (i.e.,  $\text{-C(O)-}$ ) is also open-ended.

b. Claims 32 and 34 are rejected as being vague and indefinite because the term "bone diseases" is indefinite in scope. No specific bone diseases are positively recited. Note that the specification, at page 2, lines 20 - 24, proffers osteoporosis, malignant hypercalcemia, and Paget's disease as diseases that instant invention is suggested to treat.

***Allowable Subject Matter***

3. Claim 36 is allowed. The closest prior art is Ichihara *et al* of record who teach various epoxysuccinimide derivatives that contain an oxo group (e.g.,  $\text{=O}$ ) corresponding to  $\text{Y}^1/\text{Y}^2$  and is thus distinct from claimed compounds of the instant invention that contain instead an  $\text{-O-}$  linkage at  $\text{Y}^1$ . Therefore, nothing in the prior art of record nor references from a search in the pertinent art area teach the epoxysuccinimide derivatives of the instant invention.

The Examiner notes that numerous references were apparently filed with instant application, but which do not appear on a form PTO-1449. As the previous examiner suggested, if applicants wish to make said references of record, then they should submit an Information Disclosure Statement listing said references on a form PTO-1449.

Any inquiry concerning this communication from the examiner should be directed to Steven M. Reid whose telephone number is (703) 308-7023. The examiner can normally be reached on Monday through Friday from 7:30 AM to 4:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

SMR

Steven M. Reid, Ph.D.  
Examiner  
Art Unit 1624

Mukund J. Shah

Mukund J. Shah  
Supervisory Patent Examiner  
Art Unit 1624